DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 9, 2015

Ivoclar Vivadent AG
c/o Ms. Donna Marie Hartnett
Ivoclar Vivadent, INC
175 Pineview Drive
Amherst, NY 14228

Re: K150393
Trade/Device Name: Tetric EvoFlow Bulk Fill
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: II
Product Code: EBF
Dated: March 4, 2015
Received: March 10, 2015

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K150393

Device Name
TETRIC EVOFLOW BULK FILL

Indications for Use *(Describe)*

– As initial layer / first increment in Class I and II composite restorations in permanent teeth
– Restorations in deciduous teeth

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Tetric EvoFlow Bulk Fill

Rev. 3.6.15

Contact: Donna Marie Hartnett, Ivoclar Vivadent, Inc.
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Date Prepared: June 3, 2015

Proprietary Name: **Tetric EvoFlow Bulk Fill**

Classification Name: Material, Tooth Shade,Resin (872.3690)
(Classification Code EBF)

Predicate Device: Tetric EvoCeram Bulk Fill (K111958)

Device Description: Tetric EvoFlow® Bulk Fill is a flowable, light-curing radiopaque composite. As its opacity increases during polymerization, it is also suitable for discolored tooth structure. It is applied in increments of up to 4 mm as an initial layer in Class I and II restorations.
Tetric EvoFlow Bulk Fill is intended for use as a dental filling material.

Intended Use:
– As initial layer / first increment in Class I and II composite restorations in permanent teeth
– Restorations in deciduous teeth

Comparison to Predicate: The predicate device to which Tetic EvoFlow Bulk Fill has been compared is Tetric EvoCeram Bulk Fill (K111958). For this application, Tetric EvoFlow Bulk Fill has been compared to its predicate with regard to chemical composition, physical properties, operating principles and indications for use. The comparison shows that Tetric EvoFlow Bulk Fill is substantially equivalent to the predicate device.

Predicate – Tetric EvoCeram Bulk Fill (K111958)	Subject Device
Tetric EvoCeram Bulk Fill is a light-curing, radiopaque dental filling composite. The special features are: - It is applied in increments of up to 4 mm, saving the dentist time	Tetric EvoFlow Bulk Fill is a flowable, light-curing radiopaque dental filling composite. The special features are: - it is applied in increments of up to 4 mm, saving the dentist time - that its opacity increases during polymerization. It is intended to be a dentin replacement and is also suitable for discolored tooth structure
Indications for Use • Restorations of deciduous teeth • Restorations in the posterior region (Classes I and II) • Class V restorations (cervical caries, root erosion, wedge-shaped defects) • Extended fissure sealing in molars and premolars	Indications for Use • As initial layer / first increment in Class I and II composite restorations in permanent teeth • Restorations in deciduous teeth The indications are reduced because the material has been designed with an opacity similar to dentin. Flowables are often used by dentists as luting composites and this is excluded by the subject device.
Working principle - Shade selection - Isolation - Cavity preparation - Pulp protection / base - Application of the matrix / interdental wedge - Conditioning / application of the bonding agent - Application of Tetric EvoCeram Bulk Fill in layers of maximum 4mm polymerizing each layer. - Finishing / checking the occlusion / polishing	Working principle remains unchanged from predicate. The consistency has been changed to flowable for easy application as the first layer of a restoration. An optimization of the device makes it possible to have a materials which is transparent enough to be polymerized in 4mm layer but them sufficiently opaque to achieve the esthetics of dentin.

Technological Characteristics and Testing Summary: FDA Guidance Document for Dental Composite Resin Devices dated October 26, 2005 was followed in connection with this application.

The device was evaluated for biocompatibility in accordance with ISO 10993-1:2009 and EN ISO 7405:2008. The device was tested for cytotoxicity and Mutagenicity. In addition, the photoinitiator was tested in a cytotoxicity assay in vitro. Biocompatibility was further assessed based on a comparison to the predicate device and review of the literature.

The device was tested in accordance with ISO 4049 *Dentistry – Polymer-based restorative materials (ISO 4049:2009)* as a Type 1, Class 2 restorative. The following properties were tested and compared to the predicate:

Flexural Strength
Layer thickness/Curing Depth
Sensitivity to ambient light
Water Sorption
Solubility
Radiopacity
Transparency
Flexural Modulus

The specification criteria for sensitivity to light and radiopacity have been raised so that the product achieves more than required by ISO 4049. Transparency of the subject device is reduced because of its indication as a dentin replacement. A difference in flexural modulus was found and reflects the difference in consistency of the subject device from the predicate.

Both products are applied in a maximum layer thickness of 4 mm. The performance of the subject device compared to the predicate was also evaluated using the Vickers hardness profile and the results were equivalent.

Tetric EvoFlow Bulk Fill is a flowable version of the predicate device, Tetric EvoCeram Bulk Fill. The composition has been optimized to achieve the desired consistency and translucency. Overall the performance and biocompatibility are not significantly different.

CONCLUSION: In conclusion, Tetric EvoFlow Bulk Fill is substantially equivalent to the predicate device, Tetric EvoCeram Bulk Fill.